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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/612,862 | 07/03/2003 | Leonard S. Schultz | 14656 | 4394 |
| 7590 | 01/10/2005 | | EXAMINER | |
| David E. Bruhn DORSEY & WHITNEY LLP Intellectual Property Department 50 South Sixth Street, Suite 1500 Minneapolis, MN 55402-1498 | | | GREENE, JASON M | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1724 | | |
| DATE MAILED: 01/10/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/612,862 | SCHULTZ, LEONARD S. | |
| | Examiner | Art Unit | |
| | Jason M. Greene | 1724 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 03 July 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 8/29/03.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Inventorship

1. In view of the papers filed 30 January 2004, the inventorship in this nonprovisional application has been corrected under 37 CFR 1.48(f)(1) by the deletion of Jeffrey K. Drogue as a joint inventor. Specifically, the inventorship has been corrected since the declaration filed 30 January 2004 is the first executed declaration filed in this application. The Examiner notes that the PTO PALM data has been updated to reflect the corrected inventorship.

Specification

2. In view of the above noted inventorship correction, the Examiner suggests Applicants amend the introductory paragraph to the specification by deleting Jeffrey K. Drogue as a joint inventor.

Priority

3. The Examiner notes that the Application Data Sheet filed 03 July 2003 recites the instant application claiming priority benefit of a prior provisional application and being a continuation-in-part of two prior applications, while the declaration filed 30 January 2004 does not claim priority benefits of any prior applications. Therefore, since 37 CFR

1.76(d)(1) states that inconsistent information supplied by both an application data sheet and an oath or declaration is governed by the latest submitted information, the instant application does not claim the priority benefits of the prior domestic applications. Additionally, the Examiner further notes that it appears as though Applicants intentionally disclaimed the priority benefits since the paragraph of the specification referencing the prior domestic applications was deleted in the preliminary amendment filed 30 January 2004.

Drawings

4. The drawings are objected to under 37 CFR 1.84(p)(1) because reference character S in Fig. 13 is enclosed within inverted commas (i.e. “ ”). Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Additionally, Applicants are reminded that the specification should be likewise corrected by changing reference characters “S” to read as S.

Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be

necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claims

5. Claims 8 and 9 recite the phrase "The filter of claim 1 further comprising..." in line 1. However, claim 1 is directed to a system for removing vapors and particles from a pressurized surgical cavity, wherein the system comprises a filter and several other recited components. For examination purposes, the Examiner has assumed that claims 8 and 9 were intended to retain all of the structural components recited in claim 1 while further defining the filter. If this assumption is correct, the Examiner suggests Applicants rewrite the preamble of claims 8 and 9 as "The system of claim 1, wherein the filter comprises" to improve the clarity and precision of the claim language.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4, 9, 11-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman in view of Wortrich et al.

With regard to claim 1, Berman discloses a system (70) for removing vapors from a pressurized surgical cavity comprising a fluid pathway (76,80,82) including an intake end (end of 76 connected to handpiece 26) and a return end (end of 82 connected to handpiece 26), both ends being in fluid communication with a pressurized surgical site (the chest cavity of patient 14), a flow generating device (pump 74) in fluid communication with the fluid pathway and located between the intake end and the return end, a filter (not shown, see col. 4, lines 11-18) in fluid communication with the fluid pathway and located between the intake end and the return end, wherein the flow generating device generates a flow of fluid comprising insufflation gases in Fig. 1 and col. 3, line 28 to col. 4, line 32.

Berman does not disclose the flow rate through the system or the flow rate creating a minimal total system pressure loss.

Wortrich et al. discloses using a low flow rate of 1 to 6.5 liters per minute for insufflation to avoid dehydration and cooling of the patient in col. 9, lines 47-62.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the 1 liter per minute flow rate of Wortrich et al. into

the system of Berman to avoid dehydration and cooling of the patient, as suggested by Wortrich et al. in col. 9, lines 47-62.

With regard to claim 2, using the low flow rate of Wortrich et al. in the system of Berman will inherently create a minimum total system pressure loss since pressure loss is proportional to flow rate.

With regard to claim 3, the claimed range of approximately 2.5 to approximately 4.0 liters per minute is seen as lying within the prior art range of 1 to 6.5 liters per minute. Therefore a prima facie case of obviousness exists which must be overcome through a showing of unexpected or unobvious results. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) and MPEP 2144.05[R-1].

With regard to claim 4, using the low flow rate of Wortrich et al. in the system of Berman will inherently create a minimum total system pressure loss since pressure loss is proportional to flow rate.

With regard to claim 9, since Berman discloses the filter being provided to capture particulate matter contained in the gas in col. 4, lines 14-15, the filter inherently contains a particulate removing media.

With regard to claims 11 and 17, Berman discloses the flow generating device comprising a positive displacement (peristaltic) pump that generates a flow that is substantially steady in col. 4, lines 4-6 and col. 5, lines 3-14.

With regard to claims 12 and 13, the system of Berman, including the flow generating device and filter, is inherently capable of undergoing sterilization since it is designed for use in surgical procedures.

With regard to claim 14, even though Berman does not explicitly teach the flow generating device being incapable of generating a spark, one of ordinary skill in the art at the time the invention was made would have recognized the need to design the flow generating device (the peristaltic pump 74) and pump console (72) such that the flow generating device would be incapable of generating a spark (such as by containing all electrical connections within an air-tight chamber of the pump console) since the system is intended for use in oxygen-rich environments such as operating rooms. The Examiner notes that the limitation "incapable of generating a spark" has been interpreted to mean that the flow generating device is designed such that it can not create a spark in the atmosphere where the system is being employed while the system is in operation. This interpretation is in view of Applicants' disclosure of the pump being flame proof in page 6, lines 1-3 of the instant specification.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berman and Wortrich et al. as applied to claim 1, and further in view of Schultz et al. '316.

Berman and Wortrich et al. do not disclose the filter including a water trap.

Schultz et al. '316 discloses a similar system comprising a filter (16) including a water trap (55) in Fig. 12 and col. 4, line 60 to col. 5, line 31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the water trap of Schultz et al. '316 into the filter of Berman to provide an area or region where water vapor contained in the gas can condense and settle without effecting the efficiency of the filter, as suggested by Schultz et al. '316 in col. 5, lines 6-10.

The applied Schultz et al. '316 reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29,

1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

9. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman and Wortrich et al. as applied to claim 1, and further in view of Schultz et al. '259.

With regard to claim 7, Berman and Wortrich et al. do not disclose the system further comprising a valve adapted to control the fluid flow.

Schultz et al. '259 discloses a similar system comprising a valve (17) adapted to control the fluid flow in Figs. 5 and 7, col. 3, lines 55-63 and col. 5, lines 28-32.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the valve of Schultz et al. '259 into the system of Berman and Wortrich et al. to allow the fluid flow to be controlled, as suggested by Schultz et al. '259 in col. 5, lines 28-32.

With regard to claim 8, Berman and Wortrich et al. do not disclose the filter comprising an odor removing media.

Schultz et al. '259 discloses a similar system wherein the filter comprises an odor removing media (34) adapted to control the fluid flow in Fig. 3 and col. 4, lines 1-21.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the odor removal media of Schultz et al. '259 into the filter of Berman and Wortrich et al. to allow odorous gases to be removed from the gas flow, as is well known in the art.

10. Claims 10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman and Wortrich et al. as applied to claim 1, and further in view of Sancoff et al.

With regard to claim 10, Berman and Wortrich et al. do not disclose the flow generating device being battery powered.

Sancoff et al. teaches using battery power to operate peristaltic pumps in col. 2, lines 4-9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the battery power of Sancoff et al. into the peristaltic pump of Berman and Wortrich et al. to provide a flow generating device that operates independent of the building AC electrical supply.

With regard to claim 16, the system of Berman, Wortrich et al. and Sancoff et al. is operable without being coupled to any device remote from the location of its use since the flow generating device is battery powered.

11. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. '259 in view of Berman.

With regard to claims 1-4, Schultz et al. '259 discloses a system for removing vapors and particulates from a pressurized surgical cavity (S) comprising a fluid pathway (20,18) including an intake end (20) in fluid communication with a pressurized surgical site, a flow generating device (48) in fluid communication with the fluid pathway, and a filter (16) in fluid communication with the fluid pathway, wherein the flow generating device generates a flow through the system of 3.8 liters per minute for a fluid comprising insufflation gases to create a minimal total system pressure loss in Figs. 1 and 7 and col. 3, line 50 to col. 5, line 58.

Schultz et al. '259 does not disclose the fluid pathway including a return end in fluid communication with the pressurized surgical site or the flow generating device or filter being located between the intake end and the return end.

Berman discloses a similar system comprising a fluid pathway (76,80,82) including an intake end (end of 76 connected to handpiece 26) and a return end (end of 82 connected to handpiece 26), both ends being in fluid communication with a pressurized surgical site (the chest cavity of patient 14), a flow generating device (pump 74) in fluid communication with the fluid pathway and located between the intake end and the return end, a filter (not shown, see col. 4, lines 11-18) in fluid communication with the fluid pathway and located between the intake end and the return end in Fig. 1 and col. 3, line 28 to col. 4, line 32.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the return line and gas recirculation of Berman into the system of Schultz et al. '259 to better maintain pressure with the surgical cavity at a desired level, as suggested by Berman in col. 1, line 59 to col. 2, line 48.

With regard to claims 5 and 15, Schultz et al. '259 discloses the system, including the flow generating device, being disposable in col. 5, lines 5-8. The flow generating device is inherently sterile prior to use since it is designed for use in surgical procedures.

With regard to claim 6, Schultz et al. '259 discloses the filter comprising a water trap (55) in Fig. 12 and col. 4, line 60 to col. 5, line 31.

With regard to claim 7, Schultz et al. '259 discloses the system further comprising a valve (17) adapted to control the fluid flow in Figs. 5 and 7, col. 3, lines 55-63 and col. 5, lines 28-32.

With regard to claims 8 and 9, Schultz et al. '259 discloses the filter comprising an odor removing media (34) and a particulate removing media (36) in Fig. 3 and col. 4, lines 1-21.

With regard to claim 10, Schultz et al. '259 discloses the flow generating device being battery powered in col. 5, lines 39-45.

With regard to claims 11 and 17, Schultz et al. '259 discloses the flow generating device comprising a positive displacement air pump having an impeller or fan that generates a flow that is substantially steady in col. 5, lines 39-45.

With regard to claims 12 and 13, the system of Schultz et al. '259, including the flow generating device and filter, is inherently capable of undergoing sterilization since it is designed for use in surgical procedures.

With regard to claim 14, even though Schultz et al. '259 does not explicitly teach the flow generating device being incapable of generating a spark, one of ordinary skill in the art at the time the invention was made would have recognized the need to design the flow generating device (48) such that it would be incapable of generating a spark (such as by installing the batteries in an air-tight chamber in the pump) since the system is intended for use in oxygen-rich environments such as operating rooms.

With regard to claim 16, Schultz et al. '259 discloses the system being operable without being coupled to any device remote from the location of its use in Figs. 1 and 3 and col. 3, line 50 to col. 5, line 58.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Petersen et al., Kopylov et al., Pruchon, Curtis et al., Shah et al. and Staten references disclose similar systems.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Greene whose telephone number is (571) 272-1157. The examiner can normally be reached on Monday - Friday (9:00 AM to 5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on (571) 272-1166. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jason M. Greene
Examiner
Art Unit 1724

Jason M. Greene
1/6/05

jmg
January 6, 2005